## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of U.S. Appln. No. : 10/736,264

: Hartig, M. et al

) Art Unit: ) Examiner: 1614

Confirmation No.: 3847

U.S. Filing Date : 12/15/2003

Title of Invention: Powdered Medicaments Containing A Tiotropium Salt And Salmeterol

Xinafoate

Attny. Docket No.: 1/1439

Mail Stop Amendment Commissioner for Patents P. O. Box 1450

Alexandria, VA 22313-1450

June 7, 2004

## TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A and B) with copies of all references cited therein. This is being submitted pursuant to 37 C.F.R. §1.56 and before the mailing of a first Office Action on the merits, pursuant to 37 CFR § 1.97(b).

It should be noted that the references listed in the Information Disclosure Statement have been cited in the International Search Report (ISR) for PCT/EP 03/13691, which corresponds to the present US application. A copy of that ISR is enclosed herewith.

			nt is being filed: 1) within three (3) months of the filling
date o	f a natio	nal application other	than a continued prosecution application under 33 C.F.R.
§1.53	(d); ii) v	vithin three (3) month	s of the date of entry of the national stage as set forth in
37 C.I	F.R. §1.4	91 in an internationa	l application; iii) before the mailing of a first Office action
on the	merits;	or iv) before the mail	ing of a first Office action after the filing of a request for
		mination under 37 C.	
C.F.R	. §1.97(l of allov	o), but before the mai vance under 37 C.F.R	ent is being filed after the time period specified in 37 ling date of: i) a final action under 37 C.F.R. §1.113, ii) a §1.311, or iii) an action that otherwise closes a Statement is being accompanied by:
Proces			ified in 37 C.F.R. §1.97(e) [see below]; or

		The fee set forth in 37 C.F.R. §1.17(p).
		The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.
	nent as s	This Statement is being filed after the period specified in 37 C.F.R. on or before payment of the issue fee. This Statement is accompanied by a pecified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R.
	1.97(e	).
	counte	Each item of information contained in the instant information disclosure tent was first cited in any communication from a foreign patent office in a expart foreign application not more than three (3) months prior to the filing of stant information disclosure statement; or
	foreig makin inform C.F.R	No item of information contained in the instant information disclosure tent was cited in a communication from a foreign patent office in a counterpart in application, and, to the knowledge of the person signing this certification after g reasonable inquiry, no item of information contained in the instant nation disclosure statement was known to any individual designated in 37. §1.56(c) more than three (3) months prior to the filing of the instant nation disclosure statement.
	□.	The fee set forth in 37 C.F.R. §1.17(p).
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count in sec	erpart aption 1.5	(d). Each item of information contained in the accompanying information tement was cited in a communication from a foreign patent office in a opplication, which communication was not received by any individual designated 6(c) more than thirty (30) days prior to the filing of the accompanying isclosure statement.

 $\boxtimes$ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

Andrea D. Small

Attorney for Applicant(s)

Reg. No. 54,859

Patent Department Boehringer Ingelheim Corp. 900 Ridgebury Road, P.O. Box 368 Ridgefield, CT 06877

Tel: (203) 798-4816

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Andrea D. Small, Reg. No. 54,859

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	Substitute for form 1449A/PTO	no persons are redui		ion unless it contains a valid OMB control num Implete if Known	
,	Substitute for form 1445/41 10		Application Number	10/736,264	
	INFORMATION DISC	CLOSURE	Filing Date	12/15/2003	
	STATEMENT BY AP		First Named Inventor	Mareke HARTIG	
	OTATEMENT BY A	. 2.07	Art Unit	1614	
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Shee	1	of 3	Attorney Docket Number	1/1439	

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (# known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		<sup>US-</sup> 5,795,594	08/18/1998	York, P. et al	
,		<sup>US-</sup> 2003/018019 A1	01/23/2003	Meade, C.J. M. et al	
		<sup>US-</sup> 2002/189610 A1	12/19/2002	Bozung, K-H. et al	
	<u> </u>	<sup>US-</sup> 2003/130300 A1	07/10/2003	Linz, G. et al	
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	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> 'Number <sup>4</sup> 'Kind Code <sup>5</sup> (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ <sup>6</sup>		
		WO 03/000241 A2	01/03/2003	BI Pharma KG				
	1	WO 03/013633 A1	02/20/2003	Glaxo Group Ltd.				
	1	WO 02/060532 A1	08/08/2002	BI Pharma KG				
	Ī	WO 02/38154 A1	05/16/2002	BI Pharma KG				
	Ī	WO 00/69468 A1	11/23/2000	BI Pharma KG	•			

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	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document  Country Code <sup>3</sup> 'Number <sup>4</sup> 'Kind Code <sup>5</sup> ( <i>il known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>			
		WO 02/30390 A2	04/18/2002	BI Pharma KG		L			
•••••	İ	WO 93/16031 A1	08/19/1993	Glaxo Group Ltd.					
	İ	WO 03/024452 A1	03/27/2003	BI Pharma KG					
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	INFO	RMATION [	DISCLOS	SURE	Filing Date	12/15/2003		
	STATEMENT BY APPLICANT				First Named Inventor	Mareke HARTIG		
	•	• —			Art Unit	1614		
		(Use as many sheets	as necessary)		Examiner Name			
_	Sheet	3	of	3	Attorney Docket Number	1/1439		

Examiner Initials*  Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  Database Accession No. 2003:353344: SHEKUNOV, B. Y. ET AL; Physical properties of supercritically-processed and micronized powders for respiratory drug delivery"; XP002277844  SHEKUNOV, B. Y., ET AL; "Aerosolisation Behaviour Of Micronised And Supercritically Processed Powders"; Aerosol Science. Bd. 34, 2003, pgs 553-568; XP002277843		NON PATENT LITERATURE DOCUMENTS	
supercritically-processed and micronized powders for respiratory drug delivery"; XPUU2277644  SHFKLINOV B. Y., ET AL: "Aerosolisation Behaviour Of Micronised And Supercritically Processed		magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SHEKUNOV, B. Y., ET AL; "Aerosolisation Behaviour Of Micronised And Supercritically Processed Powders"; Aerosol Science. Bd. 34, 2003, pgs 553-568; XP002277843		Database Accession No. 2003:353344: SHEKUNOV, B. Y. ET AL; Physical properties of supercritically-processed and micronized powders for respiratory drug delivery"; XP002277844	
	 	SHEKUNOV, B. Y., ET AL; "Aerosolisation Behaviour Of Micronised And Supercritically Processed Powders"; Aerosol Science. Bd. 34, 2003, pgs 553-568; XP002277843	

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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